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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,605	01/20/2004	Jan Weber	12013/51401	8100
23838	7590	07/09/2007	EXAMINER	
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/759,605

Applicant(s)

WEBER ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 6, 8, 12, 14-20, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9-11, 13, 21, 22 and 25-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2,4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 4 recite the limitation "the filter material" in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claim. The word material should be deleted from line 1 of claim 2 and claim 4 should recite "the filter is a material that covers....".

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5,9,11,27,30 are rejected under 35 U.S.C. 102(e) as being anticipated by Noda et al. (6534197). Noda et al. disclose (Fig. 2) a medical implant having an implant body (D) with a catalyst (C) covering the entire first surface of the implant and between a filter material (A) that also covers the entire first surface. Since the outer layer acts as a scaffold to trap tissue materials during ingrowth, it can be interpreted as a "filter." With respect to claim 11, It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to

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so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Thus, the filter is "adapted to" retard travel of white and red blood cells. Noda et al. also disclose to treat the catalyst layer which increases its surface area, col. 6, lines 27-32. Noda additionally discloses the implant is a non-polymer, col. 3, lines 48,49.

Claims 1-5,9,11,13,25,26,30 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt et al. (6217607). Fig. 3 shows a stent substrate **15** having a catalyst coated **50** thereon and a filter layer **80** on the outer area. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Thus, the filter is "adapted to" retard travel of white and red blood cells. Fig. 1 shows a stent body with struts. Alt discloses the stent is made of a non-polymer and covered with a catalyst metal, col. 7, lines 7,8. Alt discloses the outer filter is mesoporous or a ceramic-like material, col. 8, lines 6-10.

Claims 1-5,7,9,10,13,25,30 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson (5690670). Davidson discloses a medical implant with a body having a first surface covered with a catalyst such as titanium oxide, col. 7, lines 8-11. Davidson also discloses the stents can include a therapeutic agent, col. 14, lines 60-64 and col. 16, lines 48-52. Davidson also discloses that coatings applied to medical implants can be polymers and ceramics can be applied on the surface of the implant, col. 11, lines 59-66 and col. 12, lines 49-67. Davidson also discloses the use of a porous coating on the stent, col. 4, lines 56-66.

Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kula et al. (6325825). Figs. 1a-d, 2, 3a, b, 4, 6-9 all illustrate different strut patterns. Figs. 11, 12 show that the stent has a tapered cross-section. It is inherent that a strut will have a smaller area for the areas toward the outside of the stent in locations where the stent has a smaller or tapered thickness. Kula also discloses the stent is expandable, col. 4, lines 15-18.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21, 22, 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. '607 in view of Smalley et al. (2002/85968). Alt et al. is explained supra. Alt does disclose the filter material can be iridium oxide, col. 7, lines 46-48. However, Alt et al. fail to disclose alternative filter material or coverings for the composite stent. Smalley et al. teach the use of catalysts with carbon nanotubes or bucky paper coated onto to composites including implants and prostheses, paragraphs 121, 276. Smalley also teaches that the bucky paper is useful in supporting catalysts on devices (paragraph 126) and to provide a composite device resisting delamination, paragraph 14. Smalley additionally teaches the bucky paper can be used with oxides, paragraphs 94, 166, 268. Smalley also teaches that polymers can be applied to enclose the composite material and provide the bulk or support for the body framework, paragraphs 257, 259. It would have been obvious to one of ordinary skill in the art to incorporate

bucky paper and a polymer matrix as taught by Smalley et al. with the stent of Alt et al. such that it improves the adherence of the layers formed on the stent material and provide a supportive device that will not collapse or degrade.

Claims 34,35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kula et al. '825 in view of Alt et al. '607. Kula et al. is explained as before. However, Kula fails to disclose the use of a catalyst and filter. Alt is explained supra. Alt discloses the outer coating layer or oxide aids in reducing inflammation, col. 10, lines 41-47. It would have been obvious to one of ordinary skill in the art to incorporate the catalyst and filter material on the stent as taught by Alt et al. such that the stent of Kula et al. can provide a limited inflammatory response when implanted.

Response to Arguments

Applicant's arguments filed 4/24/07 have been fully considered but they are not persuasive. Applicant argues that Noda '197 fails to teach a filter since the second layer is designed to allow ingrowth of bone tissue. The Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851,1854 (Fed. Cir. 2001) and MPEP 2111.01. The Examiner is not giving the term "filter" any special definition and thus, Noda clearly

discloses a structure that can encompass a "filter". Regarding the Alt '607 reference, Applicant argues that the reference does not have a "filter" covering or containing a catalyst. The Examiner stated the stent is coated with a catalyst metal and covered with a ceramic material that is porous to act like a filter. It should be also noted that the amended language in the claims "contains a catalyst" can be interpreted that a "filter" layer can be the catalyst and act as a filter as the Alt outer layer can be interpreted also. Applicant also argues that Davidson '670 also does not comprise a "filter". However, just as Alt and Noda disclose a ceramic, Davidson does also disclose a layer that can be interpreted as a filter which is exactly what Applicant's mesoporous structure is.

Regarding the comments about the Kula '825 rejection, Applicant argued that the Kula stent structure does not have a tapered transverse cross-section. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the transverse cross-section is **radial**) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The *longitudinal* transverse cross-section of the Kula stent is tapered as Applicant admits on page 10 of the remarks submitted 4/24/07.

Applicant additionally argues that the combination of Alt and Smalley references would not result in the claimed invention because they are not a suggestion to combine.

Applicant states the Alt stent has a rough outer surface and adding the Smalley coating would destroy the function of this surface. However, it should be noted that the surface

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coating of Smalley is applied such that it results in a rough surface, see paragraphs 19,155,158. Thus, it would not destroy the function of the stent and can provide the same capability. Additionally, Applicant states the bucky paper covering would prevent the stent from functioning as a therapeutic layer. However, the bioactive catalyst in the stent of Alt would not be inhibited by the bucky paper since it can support catalysts, as mentioned by Smalley in paragraphs 59,104,126.

Applicant argued that Kula is improperly combined with Alt because it would interfere with the function of the stent design. However, as mentioned above, Alt clearly provides an advantage to incorporate the addition of the catalyst and filter for therapeutic purposes, not a surface modification. Clearly materials can be used or applied to have reduced friction or smooth surfaces, for example by polishing and thus the addition of Alt's catalyst and filter could be applied to the stent of Kula.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (8:30am-5pm) .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E. Pellegrino